IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AVENTIS PHARMA S.A., SANOFI-AVENTIS U.S., LLC Plaintiffs, v. HOSPIRA, INC Defendant.	)	Civil Action No. 07-721-GMS
AVENTIS PHARMA S.A., SANOFI-AVENTIS U.S., LLC Plaintiffs, v. APOTEX INC., APOTEX CORP., Defendants.	)	Civil Action No. 08-496-GMS

OPENING MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTION TO CONSOLIDATE FOR ALL PURPOSES

Plaintiffs Aventis Pharma S.A. and sanofi-aventis U.S., LLC (collectively, "sanofi-aventis") respectfully request that this Court consolidate the following pending actions for all purposes: *Aventis Pharma S.A. et al. v. Hospira, Inc.*, C.A. No. 07-721-GMS (the "Hospira action") and *Aventis Pharma S.A. et al. v. Apotex Inc. et al.*, C.A. No. 08-496-GMS (the "Apotex action"). These two Hatch-Waxman patent infringement actions involve the same patents and will have numerous overlapping issues of fact and law that need to be decided by this Court in a bench trial. *See Allergan, Inc. v. Alcon, Inc.*, No. 04-968, 2005 WL 3971928, at *1 (D. Del. Jul. 22, 2005) (Sleet, J.) (striking jury demand in Hatch-Waxman 505(b)(2) case when neither side sought

damages). Consolidation of these two patent cases will also preserve this Court's resources and promote consistency in the determination of the facts and application of the law in each case. Instead of conducting multiple *Markman* hearings and holding nearly identical 7-day bench trials, sanofi-aventis proposes consolidation with a slight adjustment in the current schedule in the Hospira action, and one 10-day bench trial for both cases. Irrespective of these actions, neither Hospira nor Apotex has challenged the underlying compound patent, which expires on May 14, 2010. (*See* 08-496 D.I. 8 at 5 ¶ 14.)[1]

NATURE AND STAGE OF PROCEEDINGS

Sanofi-aventis holds an approved New Drug Application for docetaxel, which is used in the treatment of five different cancers and which is marketed in over 100 countries under the proprietary name Taxotere®. (07-721 D.I. 1 ¶ 2.) Sanofi-aventis owns five United States patents listed in the FDA's Orange Book relating to Taxotere®, which, along with their expiration dates, are as follows: U.S. Patent No. 4,814,470 (May 14, 2010) (the '470 patent); U.S. Patent No. 5,698,582 (July 3, 2012) (the '582 patent); U.S. Patent No. 5,714,512 (July 3, 2012) (the '512 patent); U.S. Patent No. 5,750,561 (July 3, 2012) (the '561 patent); and U.S. Patent No. 5,438,072 (Nov. 22, 2013) (the '072 patent).

Pursuant to the Hatch-Waxman Act, Hospira filed NDA No. 22-234 seeking approval to market its own docetaxel formulation. (07-721 D.I. ¶ 9.) Hospira's NDA included a Paragraph IV certification stating Hospira's belief that four of the patents sanofi-aventis listed in the Orange Book as claiming Taxotere® are either invalid or not infringed by Hospira's formulation. *See* 21 U.S.C. §355(b)(2)(A)(iv). Hospira did not include a Paragraph IV

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[1] Counsel for defendants Apotex Inc. and Apotex Corp. (collectively, "Apotex") have informed sanofi-aventis that Apotex joins in the relief sought.

certification against U.S. Patent No. 4,814,470 (the "'470 patent"), and thus irrespective of this litigation, the earliest Hospira can receive approval to market a generic docetaxel formulation is May 14, 2010. After receiving notice of Hospira's filing, sanofi-aventis commenced the Hospira action on November 9, 2007, triggering a 30-month stay of NDA approval that expires on May 8, 2010. *See* 21 U.S.C. § 355(c)(3)(C). In the Hospira action, sanofi-aventis alleges that Hospira infringes the '512 patent and the '561 patent. Hospira has filed an answer and counterclaim alleging that the '512 and '561 patents are not infringed, invalid and/or unenforceable due to inequitable conduct.

Apotex subsequently filed its own NDA, No. 22-312, for a docetaxel formulation. (*See* 08-496 D.I. 1 ¶ 13.) Like Hospira, Apotex filed a Paragraph IV certification as to four of sanofi-aventis' Orange Book patents. (*Id.* ¶ 14.) Like Hospira, Apotex did not include a Paragraph IV certification against the '470 patent. Thus, irrespective of this litigation, the earliest Apotex can receive approval to market a generic docetaxel formulation is May 14, 2010. On August 8, 2008, sanofi-aventis commenced the Apotex action alleging that Apotex's formulation would infringe the '512 and '561 patents. Apotex has filed a answer and counterclaim very similar to Hospira's, alleging that the '512, '561, '582 and '072 patents are not infringed, and that they are invalid and/or unenforceable due to inequitable conduct. On September 18, 2008, sanofi-aventis (i) tendered to Apotex a covenant not to sue, *inter alia*, Apotex or its customers under the '072 patent and (ii) asserted the '582 patent against Apotex in its answer to Apotex's counterclaim.[2] Thus, the Hospira action involves the '512 and '561 patents and the Apotex action

[2] The '582 patent is the parent of the '512 patent. Thus, the '582 and '512 patents share nearly the same specification and many of the same claim terms.

involves the '512, '561 and '582 patents, with many of the same claims terms and the identical invalidity and unenforceability issues that are at issue in the Hospira action.

Except for the '582 patent issues (many of which will overlap with the '512 and '561 patent issues), the Hospira and Apotex actions are essentially mirror images of each other. The cases involve the same patents, the same allegations with respect to invalidity and unenforceability, and will likely involve many of the same fact and expert witnesses. Although the Court has entered a scheduling order (07-721 D.I. 20) in the Hospira action but not in the Apotex action, both cases are in their early stages. Document production in the Hospira action has commenced, although fact discovery is not scheduled to be concluded until March 27, 2009. No depositions have been noticed and expert discovery has not begun in either action. In the Hospira action, a seven-day bench trial has been scheduled to begin October 26, 2009.

ARGUMENT

Rule 42(a) of the Federal Rules of Civil Procedure provides that "[i]f actions before the court involve a common question of law or fact, the court may: (1) join for hearing or trial any or all matters at issue in the actions; (2) consolidate the actions; or (3) issue any other orders to avoid unnecessary cost or delay." The purpose of consolidation is to avoid duplication of effort during pre-trial proceedings and "to prevent conflicting outcomes in cases involving similar legal and factual issues." *In re TMI Litig.*, 193 F.3d 613, 724 (3d Cir. 1999) (citation omitted). Consolidation is meant to improve efficiency in judicial proceedings and does not change the rights of the parties. *Id.*

A common question of law or fact is a prerequisite for consolidation. *See Abbott Diabetes Care, Inc. v. Dexcom, Inc.*, C.A. No. 06-514 (GMS), 2007 WL 2892707, at *3 (Sept. 30, 2007). Once a common question is established, the decision to consolidate is discretionary, but courts often consider efficiency, expense and fairness. *Id.* In weighing consolidation, courts

consider the interests of judicial economy created by consolidation against the potential for creating new delays or prejudice. *See Rohm & Haas Co. v. Mobil Oil Corp.*, 525 F. Supp. 1298, 1309 (D. Del. 1981). Because patent infringement actions involving the same patents and multiple defendants share common issues, consolidation is appropriate to conserve judicial resources. *See, e.g., SmithKline Beecham Corp. v. Geneva Pharm., Inc.*, No. 99-CV-2926, 2001 WL 1249694 at *5 (E.D. Pa. Sept. 26, 2001) (consolidating patent infringement actions with different defendants).

I. Consolidation of the Pending Cases is Warranted.

A. Consolidation Will Preserve the Court's and the Parties' Resources.

As defined by the parties' pleadings to date, the issues of law and fact presented by these cases are nearly identical. The issues of claim construction, invalidity and unenforceability will be virtually the same in the two cases, and even though Hospira's and Apotex's formulations are different, the infringement issues will likely turn on the same claim limitations.

First, sanofi-aventis has asserted the '512 and '561 patents against both Hospira and Apotex. Patent cases involving the same patents and similar technology are especially ripe for consolidation. *See e.g., Cedars-Sinai Med. Ctr. v. Revlon Inc.*, 111 F.R.D. 24, 33 (D. Del. 1986) (consolidating cases that involved "closely related inventions" and where the relevant prior art would be the same); *Rohm and Haas*, 525 F. Supp. at 1309. Among other things, consolidation would obviate the need for two redundant *Markman* hearings.

Second, each defendant's factual allegations as to invalidity and unenforceability of sanofi-aventis' patents are very similar. In particular, Apotex apparently copied word-for-word several paragraphs of Hospira's unenforceability allegations. (*Compare* 07-721 D.I. 7 at 14 ¶¶ 29-37 *with* 08-496 D.I. 8 at 17 ¶¶ 14-22, D.I. 9 at 16-18 ¶¶ 14-22.) The parties also cite the exact same prior art that sanofi-aventis allegedly withheld during prosecution of the patents-in-suit. (*Compare* 07-721 D.I. 7 at 17-18 ¶¶ 47-48 *with* 08-496 D.I. 8 at 19-20 ¶¶ 26-27; 08-496 D.I. 9 at

18-19 ¶¶ 26-27.) The striking similarity of the parties' allegations against sanofi-aventis militate strongly in favor of consolidation. *See SmithKline Beecham*, 2001 WL 1249694, at *5 ("[i]ssues of patent validity are . . . common to all defendants whose ANDA implicates a particular patent"); *Rohm and Haas*, 525 F. Supp. at 1310 ("There is little logic in forcing the Court to educate itself on the intricate factual details and complex legal issues common to both suits on two occasions, in preparation for two separate trials.").

Third, sanofi-aventis is proposing consolidation for all purposes and perhaps the most important savings in judicial resources will be the elimination of two separate bench trials on nearly the same if not identical issues. Hatch-Waxman cases, such as the Hopsira and Apotex actions at issue here, are tried to the Court. Under the current scheduling order in the Hospira action, a 7-day bench trial is scheduled to begin on October 26, 2009. Sanofi-aventis proposes consolidation to allow for one 10-day bench trial in which all issues can be presented to the Court in one trial, instead of two trials that cumulatively would consume a greater number of trial days.

Fourth, consolidation will also preserve the parties' resources. Because the same sanofi-aventis patents are at issue in each action, many of the same witnesses will be involved in discovery and will appear at trial. This includes the inventors of the patents-in-suit and the technicians involved in the development of Taxotere®, all of whom live in France. When the issues in each case are so similar, there is no need to force these witnesses to sit for multiple depositions and trials to cover the same ground, particularly given that many of the fact witnesses in the case live in France. And, sanofi-aventis expects that the large volume of documents it will produce to both Hospira and Apotex will, for the most part, be identical.

Insofar as judicial efficiency and preservation of both resources, these actions are perfect candidates for consolidation.

B. Consolidation Will Not Cause Any Prejudice to the Defendants.

There is no prospect of undue prejudice to either defendant from consolidation.

First, in view of the fact that neither Hospira nor Apotex included a Paragraph IV certification against the '470 patent, the earliest either can receive approval to market a generic docetaxel formulation is May 14, 2010. The trial in the Hospira action is currently scheduled to begin on October 26, 2009.

Second, both actions are at an early stage—discovery in the Hospira action has barely begun, while there has been no discovery at all in the Apotex action. In any event, the fact that individual cases may be at differing stages of discovery does not preclude their consolidation. *See Internet Law Library, Inc. v. Southridge Capital Mgmt., LLC*, 208 F.R.D. 59, 62 (S.D.N.Y. Apr. 10, 2002); *Rohm and Haas*, 525 F. Supp at 1310. Courts typically have denied consolidation for undue prejudice or delay in situations where a party moves to consolidate actions when a trial date for one action was fast approaching. *See, e.g., Bruno v. Borough of Seaside Park*, No. Civ. 04-5084 (GEB), 2006 WL 2355489, at *2 (D.N.J. Aug. 14, 2006) (denying motion to consolidate two cases when one trial date was close and the other action would be in discovery for a few more months); *Syngenta Seeds, Inc. v. Monsanto Co.*, No. C-A 02-1331, 2004 WL 2002208, at *2 (D. Del. Aug. 27, 2004) (denying motion to consolidate when, *inter alia*, trial in one case was scheduled to begin within three months); *see also* 9 C. Wright, A. Miller & E. Cooper, *Federal Practice and Procedure* § 2383 (2008). That touchstone for undue delay is not present here, as the trial date in the Hospira action is still more than a year away.

CONCLUSION

For the foregoing reasons, sanofi-aventis respectfully requests that the Court grant plaintiffs' motion to consolidate the above-referenced actions for all purposes, and enter a scheduling order to govern the consolidated action.

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